

or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art." (emphasis added).

Converting base urea compounds to solvate form is conventional in the art and well known to one of ordinary skill in the art. See the previously filed Appeal Brief in support. The art is plentiful with solvates of pharmaceutical compounds. A quick search of the art reveals, for example, US Pat. 5,786,448, US Pat. 5,905,080, and US Pat. 4,379,786 all of which teach solvates of urea compounds. US Pat. 4,379,786, for example, teaches:

The preferred salt forms of I are additionally capable of forming hydrates and solvates with H₂O and certain organic solvents, respectively. Also, I and its salt forms may exist in several tautomeric forms. It is naturally intended that the various hydrates, solvates, and tautomeric forms of I be included within the scope of this invention. (emphasis added) Column 4 lines 7-13.
(US Pat. 4,379,786 was filed in 1981 by a party other than applicants of the present application.)

The language, "It is naturally intended that the various hydrates, solvates, and tautomeric forms of I be included within the scope of this invention," (emphasis added) clearly shows that even in 1981 one skilled in the art would naturally include solvates when presented with a base compound. The critical elements of the claims of the current invention are the compounds of formula I which are well defined in the specification. That the compounds of formula I are in a solvate form is not critical elements as one skilled in the art would know the compounds could form solvates and could form said solvates through routine experiments using the claimed compounds of formula I. In this regard, see the previously filed Appeal Brief, as a result of which, the allegations of lack of enablement of the solvates have been withdrawn.

As stated on page 2 of the Office Action, the subject matter of the claims must be described so as to reasonable convey to one skilled in the art that the inventors had possession of the claimed invention at the time of filing. Applicant's respectfully submit that the specification which describes in detail the compounds of formula I does reasonable convey to one skilled in the art that the inventors also had possession of the solvate forms of these compounds, as creating solvates from ureas compounds is routine in the art. As discussed above, one skilled in the art would know, "It is naturally intended that the various hydrates, solvates, and tautomeric forms of I be included within the scope of this invention," US Pat. 4,379,786 Column 4 lines 10-

13.

See *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005) where a specification gave no examples of the involved genus, i.e., nucleotide or amino acid sequences, but merely relied on prior art knowledge, and yet was held to provide an adequate written description. Similarly to *Capon*, there is no dispute here that one of ordinary skill in the art can make the claimed solvates, and, as in *Capon*, the fact that the genus of solvates is well known, involves extensive prior art, and a mature science and technology, weighs very heavily in finding the existence of a written description. When the prior art includes the information, precedent does not set a per se rule that the information must be determined afresh. *Id.* at 1358.

The specification of the present application clearly teaches the concept of solvates by disclosing specific embodiments of combinations of compounds with solvents. For example, entry 9 in table 1 on page 62 of the specification is synthesized using method B5. This method describes the desired compound being formed in solution involving the interaction between a compound and a solvent. Most, if not all of the examples given in the specification require the compounds to be synthesized in solution through the combination of compounds with solvents and therefore the specification is replete with examples showing the concept of solvates. This disclosure shows that applicants were in possession of the concept of solvate formation, and in combination with what was well known to one of ordinary skill in the art at the time of filing, discussed above, demonstrates that the applicants were in possession of the claimed subject matter at the time of filing.

In view of the above, favorable reconsideration is respectfully and courteously requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

/Ryan Pool/

Attorneys for Applicants
Ryan Pool, Reg. No. 64,615
Csaba Henter, Reg. No. 50,908

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410
Attorney Docket No.: BAYER-0006-P01
Date: December 13, 2011